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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/603,886	06/26/2000	Roy Sullivan	10546/56701	2146

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EXAMINER

QADERI, RUNA S

ART UNIT

PAPER NUMBER

3737

DATE MAILED: 06/04/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/603,886

Applicant(s)

SULLIVAN, ROY

Examiner

Runa S. Qaderi

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

Claims 33-42 are objected to because of the following informalities: Claim 33 line 6-7 recites "extending through the body lumen to a naturally occurring body orifice". This is confusing because normally an "elongated body" extends through a naturally occurring body orifice to a body lumen. The naturally occurring body orifice is the entrance port through which the invasive medical device enters the body and is then maneuvered to the desired location(s) within the body. Applicant's claim language indicated the reverse order, which is confusing.

Appropriate correction is required.

term
7.44 - looking after body in spec.
objection to specification

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 33 recitations to a "flexible body" and "a

naturally occurring body orifice" presents new matter issues that were described in the original disclosure.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 33-37 and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kreizman et al. in view of Mascuch et al. further in view of McGuckin, Jr.

Kreizman et al. teaches an apparatus for performing a medical procedure, Fig 1. The system of Kreizman et al. teaches a resection device (30), an imager (16,18) that remains outside the patients body, an image processing unit and control unit (24, 26, 36, and 37). The imager further comprises an X-ray tube (16) and an image receiver (18). The system tracks the position of the resection device via a referencing system, column 4 lines 11-18. The tissue removal device is held by removal tool guiding stage. The system control unit provides various functions of the therapy procedure. These functions include receiving boundary signals that include the region of interest to be resected from the user interface. The receiving of the boundary signals and further

display of the boundary lines in each stereotactic image is interpreted as the image data including a predetermined portion of the tissue marked for resection as claimed by the applicant, column 2 lines 19-23 and column 4 lines 6-10. The control unit includes determining the size and location of the tissue removal volume to provide control of the resection procedure, column 2 lines 34-63 and column 4 lines 34-42.

Kreizman et al. does not teach defining tissue margins by utilizing an absolute measure of tissue or a percentage of a physical dimension of the lesion, a radiopaque marker on the resection head, and an elongated body extending from a naturally occurring body orifice, and an MRI imaging device as the external imager.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to incorporate the limitations of claims 41 and 42 because Applicant has not disclosed that defining tissue margins by utilizing an absolute measure of tissue or a percentage of a physical dimension of the lesion provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the tumor boundary or tissue margin means as taught by Kreizman because it provides for control of the tissue removal procedure. Therefore, it would have been an obvious matter of design choice to modify Kreizman et al. to obtain the invention as specified in claims 41 and 42.

Mascuch et al. teaches a radiopaque marker for a stereotactic catheter. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have provided a radiopaque distal tip to the tissue removal device of Kreizman

et al. because it provides the equivalent means of detecting the position of the tissue removal device as taught by Kreizman et al. Further providing a radiopaque marker means to an invasive tool in an X-ray imaging system is a well known means of tracking the position of the device.

McGuckin Jr. teaches a surgical method and apparatus for resecting tissue. The patent teaches an elongated flexible body that is inserted via a natural occurring body orifice, column 3 lines 6-26. The method and apparatus of McGuckin Jr. facilitates endoscopically or radiologically assisted, visually guided surgery to resect diseased tissue. The invention is further not limited to any particular diagnostic imaging guidance, column 3 lines 59-65. It would have been obvious to one skilled in the art to modify Kreizman et al. such that the imaging modality used is magnetic resonance imaging. Such a modification merely involves the substitution of one well-known type of imaging modality for another. It would have been further obvious to a person of ordinary skill in the art at the time the invention was made to have provided a flexible medical device in order to reach any portion of a body lumen into which apparatus is inserted and further to insert via a naturally occurring body orifice to preclude from additional surface incision trauma to the patient as taught by McGuckin Jr.

Claims 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over over Kreizman et al. in view of Mascuch et al. further in view of McGuckin, Jr. as applied to claim 33 above, and further in view of Aida et al..

Kreizman et al. in view of Mascuch et al. further in view of McGuckin, Jr. does not teach further providing an alarm system in the controlling mechanism. Aida et al. teaches providing a control tissue therapy system that includes an alarming means to notify user of a deviation from the treatment plan. The alarming means can be either one or both of an alarm sound and a display message, column 12 lines 26-33. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to further incorporate the alarming means of Aida et al. into the system of Kreizman et al. in view of Mascuch et al. further in view of McGuckin, Jr. because it allows for controller of therapy procedure as taught by Aida et al. Further the alarming means is an additional function for controlling the therapy procedure as already taught by Kreizman et al. in view of Mascuch et al. further in view of McGuckin, Jr.

Response to Arguments

Applicant's arguments with respect to claims 33-42 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

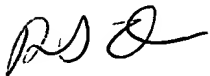
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

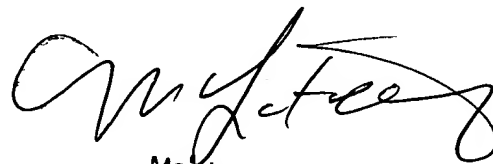
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Runa S. Qaderi whose telephone number is (703) 308-8155. The examiner can normally be reached on Mon-Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marvin Lateef can be reached on (703) 308-3256. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 746-7289 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



RSQ
May 19, 2003



Marvin M. Lateef
Supervisory Patent Examiner
Group 3700